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10/644,106	08/20/2003	Johan F.M. Gijsbers	11738.00120	6509

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EXAMINER	
WACHTEL, EMILY L	

ART UNIT	PAPER NUMBER
3767	

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11/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/644,106	GIJSBERS ET AL.	
	Examiner	Art Unit	
	EMILY WACHTEL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,25,27-31,33-35,37-43 and 45-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *30,38-40,42,43,45 and 46* is/are allowed.

6)☒ Claim(s) *23,25,27,28 and 49* is/are rejected.

7)☒ Claim(s) *29, 31, 33-35, 37, 41, and 47-49* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:

Claims 29, 31, 33-35, 37, 41, and 47-49 include claim elements "means for measuring, adjusting, pumping, calculating, filtering, treating, modifying, and monitoring" which are means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. The written description only implicitly or inherently sets forth the corresponding structure, material, or acts that perform the claimed function.
Pursuant to 37 CFR 1.75(d) and MPEP 608.01(0) and 2181, applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites the corresponding structure, material, or acts that perform the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(c) State on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function.

Appropriate Correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 49 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim element "means for diagnosing an epileptic condition in a patient" is means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts that perform the claimed function. There is insufficient disclosure for the means for diagnosing. A bare statement that known techniques or methods can be used is not sufficient disclosure.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP 2181 and 608.01(o).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osterholm (U.S. Patent 4,445,500) in view of Mayevsky (U.S. Patent 5,685,313).

With regard to claim 23, Osterholm teaches a system for controlling epileptic seizures comprising: a) a brain fluid pumping mechanism (Figure 13 the pumping mechanism is taken to encompass all individual pumps contributing to the fluid pumping in this instance pump 111 is

being considered, Col. 12 lines 17-19), having an input, coupled to a patient's brain for extracting brain fluid, and having an output (Figure 13 input is connected to the nutrient emulsion reservoir 100 - a source other than the patient's brain and an output connected to the chemical balancing unit 110); b) a fluid ion adjustment mechanism coupled to said output of said brain fluid pumping mechanism (In Figure 13 the ion adjustment mechanism is taken to be the chemical balancing unit 110, it is connected to the output of pump 111. Further in Figure 1, fluid from the brain is monitored for potassium and sodium ion concentrations - monitor 34 Col. 13 lines 46-50, in this diagram chemical balancing, taken to be ion adjustment, is at unit 12. Col. 15 lines 38-41 - sodium, potassium, calcium, magnesium, and chloride ions are balanced in the nutrient emulsion, it is taken that these ions would be balanced in the chemical balancing unit.), said fluid ion adjustment mechanism having an output from which modulated ion-content fluid is produced (Figure 13 - the balanced fluid is returned to the nutrient emulsion reservoir 100); c) a catheter, having an input coupled to the output of said ion adjustment mechanism and having an output inserted into a predetermined region of a patient's brain (Figure 13 - catheter 120 is connected to the nutrient emulsion reservoir which is the output for the fluid from the ion adjustment mechanism and is output into the patients brain, Col. 12 lines 30-31 and 34-35), whereby brain fluid is extracted from a patient's brain, ion-concentration of said fluid is adjusted and said brain fluid is re-injected into said brain (fluid is injected into the brain and continuously circulated and withdrawn, as it is withdrawn it is continuously monitored, controlled, and re-injected, Col. 6 line 26, Col. 14 lines 3-4, lines 58-60, claim 1 part d). Osterholm does not specifically disclose computer control with stored programming which controls the pumping mechanism. However, Osterholm does disclose that the device uses pumping mechanism which are 'on line' and a

closed loop process (Col. 12 lines 14-16). Further Osterholm discloses that the pump can be automatically shut down in response to an alarm (Col. 14 lines39-42). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use computer control with stored programming to control the pump in the device of Osterholm because Osterholm discloses the pump being on line and using closed loop control. Further, it has been held the broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192. As stated above, the ion concentration in the device of Osterholm is monitored but Osterholm does not disclose an electrical probe which provides electrical output related to the ion-concentration. However, Mayevsky teaches a probe for insertion into the brain (Fig. 5, Col. 9 lines 35-40) which measures the ion concentration of the brain and output the data (Col. 9 lines 38-46, Col. 13 lines 2-3) and further that probes are known in the art for electrically measuring brain parameters (Col. 3 lines 3-5). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use an electrical probe in the device of Osterholm to measure the electrical conductivity because Mayevsky teaches that such have proven successful in the art for measurement and output of brain function parameters including ion concentration.

With regard to claim 25, Osterholm in view of Mayevsky teach electrical output of ion concentration as above. The device provides an output related to the measurement of ion-concentration of the brain as the fluid is monitored (Fig. 1 output monitor 34). Further, Osterholm teaches automatic chemical control which balances ion concentrations, Col. 14 lines 60-66, Col. 15 lines 38-41). Osterholm does not specifically disclose computer control. However, Osterholm does disclose an alarm which may automatically disable the system in the

event of chemical imbalance (Col. 15 lines 1-4) and that chemical balancing is done in a closed loop process (Col. 12 lines 13-14). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use computer control with stored programming to control the pump in the device of Osterholm because Osterholm discloses automatic chemical balancing control. Further, it has been held the broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

6. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osterholm (U.S. Patent 4,445,500) as applied to claim 25 above, and further in view of applicant admitted prior art (AAPA).

With regards to claims 27 and 28, Osterholm discloses a system substantially as claimed. Osterholm does not specifically disclose using a membrane potential equation. However, AAPA discloses using the Goldman equation as a well-known equation for calculating the membrane potential (Page 9 [23]), therefore it would have been obvious to a person of ordinary skill in the art at the time the invention was made to calculate the ion concentration using such a membrane potential equation in the device in Osterholm because APPA teaches it is an art recognized means for monitoring the ion concentration so the system can determine how the fluid needs to be chemically balanced.

7. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osterholm (U.S. Patent 4,445,500) in view of applicant admitted prior art (AAPA) and further in view of Lucido et al. (U.S. Patent 6,402,941).

With regard to claim 49, Osterholm teaches a device which re-circulates fluid through the brain which is chemically balanced and filtered (Col. 14 lines 61-62, chemical balancing Fig. 1 unit 12). The device in Osterholm does not disclose what chemical balancing occurs to balance the ion concentration of the fluid. However, AAPA discloses that using ion exchange mechanisms of filtration and chemical treatment are well-know methods in the art for adjusting the ion concentration of a fluid (Page 6 [17]). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use filtering or chemical treatment to balance the ion concentration in the device of Osterholm because AAPA teaches it is an art recognized means for doing so in order to balance the fluid to the appropriate desired ion concentration. In the device of Osterholm fluid is injected into the brain and continuously circulated and withdrawn, as it is withdrawn it is continuously monitored and controlled (Col. 6 line 26, Col. 14 lines 3-4, lines 58-60, claim 1 part d). It is pumped into a localized region of the patient's brain in the lateral ventricle (Figure 1 ventricle 20, Col. 12 lines 30-35). Further, in the device of Osterholm fluid that was injected into the brain circulates and then is withdrawn and monitored, effectively the brain fluid proximate to the region where the fluid in Osterholm is injected is monitored (Col. 13 lines 44-47). Osterholm teaches the fluid is monitored for ion concentrations however, Osterholm does not disclose a means for monitoring as in how the monitoring device actually monitors the ion concentration. However, as a means for monitoring, Lucido teaches a conductivity sensor which measures ion concentration (Col. 8 lines 42-43). It

would have been obvious to a person of ordinary skill at the time the invention was made to use conductivity as a means for monitoring ion concentration in the device of Osterholm because Lucido teaches it is a known method of measuring ion concentrations and would yield the predictable result of measuring the ion concentration so that the device of Osterholm can monitor them. Osterholm does not disclose means for diagnosing an epileptic condition in a patient. However APPA states that epileptic conditions in a patient can be diagnosed using any suitable apparatus and/or method, which are well known in the art (Page 4 [10]). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use epileptic diagnostic means because AAPA teach that such are well known in the art.

Allowable Subject Matter

8. Claim 29-31, 33-35, and 37-43, and 45-48 are allowed pending correction of the above objections regarding 112 sixth paragraph. The prior art of record does not teach or otherwise render obvious at the time the invention was made a fluid pumping mechanism with means for adjusting the delivery of the modulated ion-content fluid based upon the measured electrical conductivity of the brain fluid.

Response to Arguments

9. Applicant's arguments with respect to claim 23 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY WACHTEL whose telephone number is (571) 270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Wachtel/
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